



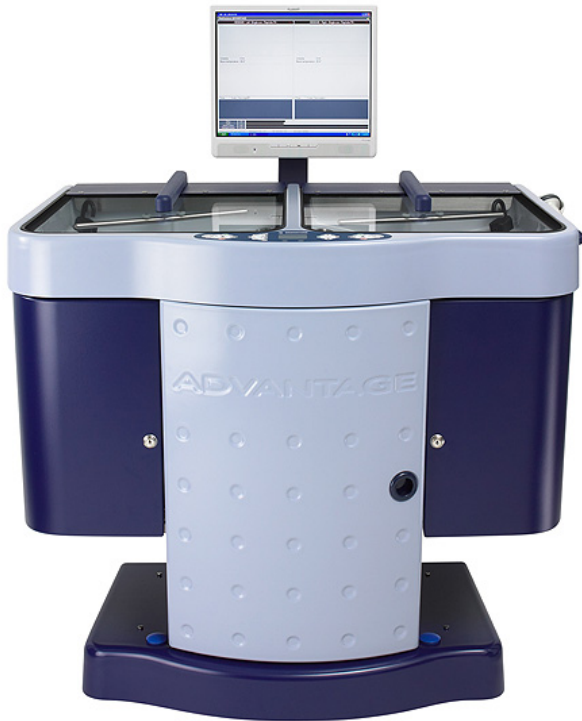
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# Agenda

- PURPOSE: Validation: High Level Disinfection of Endoscopes, Using a Logic Based Approach
- MEDIVATORS Advantage Plus AER
- Rapicide PA Efficacy Summary
- Preliminary Scope Tests
- Simulated and Clinical Scope Test
- Questions

# MEDIVATORS® ADVANTAGE® PLUS

Endoscope Reprocessing System



## Rapicide PA Disinfectant

- 5 minutes at 30°C
- Minimum recommended concentration (MRC)= 850 ppm Peracetic Acid
- Germicide is aged  $\geq 6$  months
- Representative endoscopes chosen to confirm testing of long, small and complex channels
- Only disinfection phase is used, no wash or rinse in this test method

Figure 1: Medivators Advantage Plus AER

# Simulated Use

- Pre-cleaning performed according to manufacturer's instructions
- Scope inoculation
  - *M. terrae* ( $\geq 6$ -logs per scope) & organic load (bovine serum)
    - The distal end is placed in test tube and is submerged in inoculum for each channel
    - Exterior inoculation
- Dry for 1-1.25 hours
- Program parameters set to start at 5 min disinfection with chemistry at MRC
- Recovery of scope
  - Exterior recovery- sponge distal end of scope with neutralizer
  - Channel recovery- flush each channel with neutralizer
    - Brush biopsy channel



Figure 2: scope inoculation

## Clinical scopes

- Obtain scopes used the morning of testing from clinics
  - Pre-cleaning was performed at clinic following the clinic's standard procedure
- Reprocess scope
  - Program parameters set to start at 5 min disinfection with chemistry at nominal<sup>3</sup>
- Scope recovery same as simulated use
- Full cycle also run to prove no phase will negate disinfection

# Summary of Efficacy Test

TESTS	Organism	Results
Sporicidal	<i>Clostridium sporogenes</i> spores	Total Kill
Sporicidal	<i>Bacillus subtilis</i> spores	Total Kill
Tuberculocidal	<i>Mycobacterium bovis</i> (BCG)	Total Kill
Virucidal	Polio virus type 2	Complete Inactivation
Virucidal	Herpes Simplex virus type 1	Complete Inactivation
Virucidal	Human Immunodeficiency Virus type 1	Complete Inactivation
Fungicidal	<i>Trichophyton mentagrophytes</i>	Total Kill
Bactericidal	<i>Pseudomonas aeruginosa</i>	Total Kill
Bactericidal	<i>Staphylococcus aureus</i>	Total Kill
Bactericidal	<i>Salmonella enterica</i>	Total Kill
Simulated Use	<i>Mycobacterium terrae</i>	>6 log Reduction
In-Use	GI Tract Normal Flora	Total Kill

Table 1: Efficacy testing for Rapicide PA at 5 min contact time<sup>1</sup>

# Medivators HLDs Tested with CRE

Exposure time (minutes)	Number of survivors (CFU/ml)	Log reduction Rapicide	Number of survivors (CFU/ml)	Log reduction Rapicide PA	Number of survivors (CFU/ml)	Log reduction Rapicide OPA/28
1	<1	>6.04	<1	>6.09	<1	>6.28
3	<1	>6.04	<1	>6.09	<1	>6.28
5	<1	>6.04	<1	>6.09	<1	>6.28

Table 2: Rate-of-kill test of Rapicide, Rapicide PA and Rapicide OPA/28 against CRE<sup>2</sup>  
The active components are glutaraldehyde, H<sub>2</sub>O<sub>2</sub> & peracetic acid and OPA respectively

# Scope Testing

## ➤ Leak Test

- Manual
  - Hand pump leakage tester
- Automated
  - Veriscan LT Leak Detection System

## ➤ Flow/hookup Test

- Objective: ensure that there is sufficient volume of disinfectant going through an individual channel during the disinfect cycle
- Digital flow meter reading for each channel
- Worse case scenario testing
  - Germicide at MRC (diluted to 850 ppm, nominal is ~ 1100 ppm PAA)
  - No wash, no rinse – disinfection phase only
  - > 1 million cfu of challenge organism added to each channel system

# Cleaning Validation

- Automated Cleaning Cycle – Advantage Plus AER
  - Intercept detergent
  - ATS soil-Gastroscope, Duodenoscope & Colonoscope
  - Respiratory test soil- Bronchoscope
  - Test markers
    1. Hemoglobin
    2. Protein
    3. Carbohydrate
- **Goal:** residuals  $<2.2 \mu\text{g hemoglobin/cm}^2$ ,  $<6.4 \mu\text{g protein/cm}^2$ ,  $<1.8 \mu\text{g carbohydrate/cm}^2$



## Results of Cleaning Validation

Scope	Protein		Carbohydrate		Hemoglobin	
	Manual	Adv. Plus	Manual	Adv. Plus	Manual	Adv. Plus
Broncho	2.02	1.76	1.02	1.04	1.44	1.72
Gastro	1.10	0.73	0.35	0.45	0.31	0.43
Colono	0.90	0.44	0.22	0.21	0.28	0.29
Avg. in	ug/cm <sup>2</sup>	ug/cm <sup>2</sup>	ug/cm <sup>2</sup>	ug/cm <sup>2</sup>	ug/cm <sup>2</sup>	ug/cm <sup>2</sup>
Accept. criterion	6.4 ug/cm <sup>2</sup>		1.8 ug/cm <sup>2</sup>		2.2 ug/cm <sup>2</sup>	

Table 3: Cleaning validation results for manual cleaning and Advantage Plus

## Conclusion

- HLDs are effective against all listed microbes except high concentrations of bacterial endospores – germicide used according to label instructions, will be efficacious
- The endoscope must be properly cleaned and maintained for AER and germicide to function correctly
- Leak testing and flow testing are needed to assure proper flow rate to intact endoscope

# References

1. Medivators. High-Level Disinfectant Rapicide PA. Available at: <http://www.medivators.com/sites/default/files/minntech/documents/50096-959%20REV%20D.pdf>. Accessed May 1, 2015.
2. Medivators. Product Bulletin. Available at: <http://www.medivators.com/sites/default/files/minntech/documents/50098-787%20REV%20A.pdf>. Accessed May 1, 2015.
3. FDA. Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High-Level Disinfectants. January 3, 2000. Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073773.htm>. Accessed May 4, 2015

# Questions?